Title: Leadless Pacemakers (CAG-00448N)

Decision: The Centers for Medicare and Medicaid (CMS) will cover leadless pacemakers through Coverage with Evidence Development (CED).

What this means: Leadless pacemakers are considered an experimental procedure. However, Medicare recently determined that leadless pacemakers will be covered when done as part of a Medicare approved clinical study. Medicare will also cover, in prospective longitudinal studies, leadless pacemakers that are used in accordance with the FDA approved label for devices that have either an associated ongoing FDA approved post-approval study, or completed an FDA post-approval study.

Leadless pacemakers are non-covered outside of Medicare approved studies.

Effective: 1/18/17

For more information, contact Customer Services at the phone number on your member ID card.

This announcement can be found at: Leadless Pacemakers

Attention. If you need free help interpreting this document, call the above number.

ያስተውሉ፡ ካለምንም ክፍያ ይህንን ዶኩመንት የሚተረጉምሎ አስተርጓሚ ከፈለጉ ከላይ ወደተጻፈው የስልክ ቁጥር ይደውሉ።

ملاحظة: إذا أردت مساعدة مجانية لترجمة هذه الوثيقة، اتصل على الرقم أعلاه.

သတိ။ ဤစာရွက်စာတမ်းအားအခမဲ့ဘာသာပြန်ပေးခြင်း အကူအညီလိုအပ်ပါက၊ အထက်ပါဖုန်းနံပါတ်ကိုခေါ် ဆိုပါ။

កំណត់សំគាល់ ។ បើអ្នកត្រូវការជំនួយក្នុងការបកប្រែឯកសារនេះដោយឥតគិតថ្លៃ សូមហៅទូរស័ព្ទតាមលេខខាងលើ ។

請注意,如果您需要免費協助傳譯這份文件,請撥打上面的電話號碼。

Attention. Si vous avez besoin d'une aide gratuite pour interpréter le présent document, veuillez appeler au numéro ci-dessus.

Thoy ua twb zoo nyeem. Yog hais tias koj xav tau kev pab txhais lus rau tsab ntaub ntawv no pub dawb, ces hu rau tus najnpawb xov tooj saum toj no.

ဟ်သူဉ်ဟ်သးဘဉ်တက္၊ စဲနမ္၊လိဉ်ဘဉ်တ၊မၤစၢၤကလီလ၊တ၊်ကကျိုးထံဝဲ¢ဉ်လံာ် တီလံာ်မီတခါအံၤနူဉ်,ကိုးဘဉ်လီတဲစိန္နီ၊ဂံ၊်လ၊ထးအံၤနူဉ်တက္၊

알려드립니다. 이 문서에 대한 이해를 돕기 위해 무료로 제공되는 도움을 받으시려면 위의 전화번호로 연락하십시오.

້ ໂປຣດຊາບ. ຖ້າຫາກ ທ່ານຕ້ອງການການຊ່ວຍເຫຼືອໃນການແປເອກະສານນີ້ຟຣີ, ຈົ່ງໂທຣໄປທີ່ໝາຍເລກຂ້າງເທີງນີ້.

Hubachiisa. Dokumentiin kun tola akka siif hiikamu gargaarsa hoo feete, lakkoobsa gubbatti kenname bilbili.

Внимание: если вам нужна бесплатная помощь в устном переводе данного документа, позвоните по указанному выше телефону.

Digniin. Haddii aad u baahantahay caawimaad lacag-la'aan ah ee tarjumaadda qoraalkan, lambarka kore wac.

Atención. Si desea recibir asistencia gratuita para interpretar este documento, llame al número indicado arriba.

Chú ý. Nếu quý vị cần được giúp đỡ dịch tài liệu này miễn phí, xin gọi số bên trên.

LB2 (8-16)

American Indians can continue or begin to use tribal and Indian Health Services (IHS) clinics. We will not require prior approval or impose any conditions for you to get services at these clinics. For enrollees age 65 years and older this includes Elderly Waiver (EW) services accessed through the tribe. If a doctor or other provider in a tribal or IHS clinic refers you to a provider in our network, we will not require you to see your primary care provider prior to the referral.

Civil Rights Notice

Discrimination is against the law. UCare does not discriminate on the basis of any of the following:

- Race
- Color
- National Origin
- Creed
- Religion
- Sexual Orientation
- Public Assistance Status
- Age
- Disability (including physical or mental impairment)

- Sex (including sex stereotypes and gender identity)
- Marital Status
- Political Beliefs
- Medical Condition
- Health Status
- Receipt of Health Care Services
- Claims Experience
- Medical History
- Genetic Information

<u>Auxiliary Aids and Services.</u> UCare provides auxiliary aids and services, like qualified interpreters or information in accessible formats, free of charge and in a timely manner, to ensure an equal opportunity to participate in our health care programs. **Contact** UCare at 612-676-6500 (voice) or 1-866-457-7144 (voice), 612-676-6810 (TTY), or 1-800-688-2534 (TTY).

Language Assistance Services. UCare provides translated documents and spoken language interpreting, free of charge and in a timely manner, when language assistance services are necessary to ensure limited English speakers have meaningful access to our information and services. Contact UCare at 612-676-6500 (voice) or 1-866-457-7144 (voice), 612-676-6810 (TTY), or 1-800-688-2534 (TTY).

Civil Rights Complaints

You have the right to file a discrimination complaint if you believe you were treated in a discriminatory way by UCare. You may contact any of the following four agencies directly to file a discrimination complaint.

U.S. Department of Health and Human Services' Office for Civil Rights (OCR)

You have the right to file a complaint with the OCR, a federal agency, if you believe you have been discriminated against because of any of the following:

- Race
- Color
- National Origin
- Age

- Disability
- Sex (including sex stereotypes and gender identity)

Contact the OCR directly to file a complaint:

Director

U.S. Department of Health and Human Services' Office for Civil Rights

200 Independence Avenue SW

Room 509F

HHH Building

Washington, DC 20201

800-368-1019 (Voice)

800-537-7697 (TDD)

Complaint Portal – https://ocrportal.hhs.gov/ocr/portal/lobby.jsf

Minnesota Department of Human Rights (MDHR)

In Minnesota, you have the right to file a complaint with the MDHR if you believe you have been discriminated against because of any of the following:

- Race
- Color
- National Origin
- Religion
- Creed

- Sex
- Sexual Orientation
- Marital Status
- Public Assistance Status
- Disability

Contact the **MDHR** directly to file a complaint:

Minnesota Department of Human Rights

Freeman Building, 625 North Robert Street

St. Paul, MN 55155

651-539-1100 (voice)

800-657-3704 (toll free)

711 or 800-627-3529 (MN Relay)

651-296-9042 (Fax)

Info.MDHR@state.mn.us (Email)

Minnesota Department of Human Services (DHS)

You have the right to file a complaint with DHS if you believe you have been discriminated against in our health care programs because of any of the following:

- Race
- Color
- National Origin
- Creed
- Religion
- Sexual Orientation
- Public Assistance Status
- Age
- Disability (including physical or mental impairment)

- Sex (including sex stereotypes and gender identity)
- Marital Status
- Political Beliefs
- Medical Condition
- Health Status
- Receipt of Health Care Services
- Claims Experience
- Medical History
- Genetic Information

Complaints must be in writing and filed within 180 days of the date you discovered the alleged discrimination. The complaint must contain your name and address and describe the discrimination you are complaining about. After we get your complaint, we will review it and notify you in writing about whether we have authority to investigate. If we do, we will investigate the complaint.

DHS will notify you in writing of the investigation's outcome. You have a right to appeal the outcome if you disagree with the decision. To appeal, you must send a written request to have DHS review the investigation outcome period. Be brief and state why you disagree with the decision. Include additional information you think is important.

If you file a complaint in this way, the people who work for the agency named in the complaint cannot retaliate against you. This means they cannot punish you in any way for filing a complaint. Filing a complaint in this way does not stop you from seeking out other legal or administration actions.

Contact **DHS** directly to file a discrimination complaint:

ATTN: Civil Rights Coordinator
Minnesota Department of Human Services
Equal Opportunity and Access Division
P.O. Box 64997
St. Paul, MN 55164-0997
651-431-3040 (voice) or use your preferred relay service

UCare Complaint Notice

You have the right to file a complaint with UCare if you believe you have been discriminated against in our health care programs because of any of the following:

- Race
- Color
- National Origin
- Creed
- Religion
- Sexual Orientation
- Public Assistance Status
- Age
- Disability (including physical or mental impairment)

Phone: 612-676-6500 or

1-866-457-7144 toll free

TTY: 612-676-6810 or

1-800-688-2534 toll free

Email: cag@ucare.org Fax: 612-884-2021

- Sex (including sex stereotypes and gender identity)
- Marital Status
- Political Beliefs
- Medical Condition
- Health Status
- Receipt of Health Care Services
- Claims Experience
- Medical History
- Genetic Information

Mailing address

UCare

Attn: Complaints, Appeals and Grievances

PO Box 52

Minneapolis, MN 55440-0052

ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 612-676-6500/1-866-457-7144 (TTY: 612-676-6810/1-800-688-2534).

LUS CEEV: Yog tias koj hais lus Hmoob, cov kev pab txog lus, muaj kev pab dawb rau koj. Hu rau 612-676-6500/1-866-457-7144 (TTY: 612-676-6810/1-800-688-2534).

XIYYEEFFANNAA: Afaan dubbattu Oroomiffa, tajaajila gargaarsa afaanii, kanfaltiidhaan ala, ni argama. Bilbilaa 612-676-6500/1-866-457-7144 (TTY: 612-676-6810/1-800-688-2534).

CHÚ Ý: Nếu bạn nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho bạn. Gọi số 612-676-6500/1-866-457-7144 (TTY: 612-676-6810/1-800-688-2534).

注意: 如果您使用繁體中文,您可以免費獲得語言援助服務。請致電 612-676-6500/1-866-457-7144(TTY: 612-676-6810/1-800-688-2534)。

ВНИМАНИЕ: Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода. Звоните 612-676-6500/1-866-457-7144 (телетайп: 612-676-6810/1-800-688-2534).

ໂປດຊາບ: ຖ້າວ່າ ທ່ານເວົ້າພາສາ ລາວ, ການບໍລິການຊ່ວຍເຫຼືອດ້ານພາສາ, ໂດຍບໍ່ເສັງຄ່າ, ແມ່ນມີພ້ອມໃຫ້ທ່ານ. ໂທຣ 612-676-6500/1-866-457-7144 (TTY: 612-676-6810/1-800-688-2534).

ማስታወሻ: የሚናገሩት ቋንቋ ኣማርኛ ከሆነ የትርጉም እርዳታ ድርጅቶች፣ በነጻ ሊያግዝዎት ተዘጋጀተዋል፡ ወደ ሚከተለው ቁጥር ይደውሉ 612-676-6500/1-866-457-7144 (መስማት ለተሳናቸው: 612-676-6810/1-800-688-2534).

ဟ်သျဉ်ဟ်သး-နမ့်္။ကတ်၊ ကညီ ကျိဉ်အယိ, နမၤန့်၊ ကျိဉ်အတာ်မၤစာၤလ၊ တလာာ်ဘူဉ်လာာ်စ္စား နီတမံးဘဉ်သံ့နှဉ်လီးကိုး 612-676-6500/1-866-457-7144 (TTY: 612-676-6810/1-800-688-2534).

ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zur Verfügung. Rufnummer: 612-676-6500/1-866-457-7144 (TTY: 612-676-6810/1-800-688-2534).

ប្រយ័ក្នុ៖ បើសិនជាអ្នកនិយា ភាសារ័ខ្មរ, រសវាជំនួយរ័ជ្នកភាសា ដោយមិនគិតឈ្នួល គឺអាច មានសំរាប់បំររីអ្នកា ចូរ ទូរស័ព្ទ 612-676-6500/1-866-457-7144 (TTY: 612-676-6810/ 1-800-688-2534)។

ملحوظة :إذا كنت تتحدث اذكر اللغة، فإن خدمات المساعدة اللغوية تتوافر لك بالمجان .اتصل برقم ملحوظة :إذا كنت تتحدث اذكر اللغة، فإن خدمات المساعدة اللغوية تتوافر لك بالمجان .612-676-6810/1-800-681-6612).

ATTENTION : Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelez le 612-676-6500/1-866-457-7144 (ATS : 612-676-6810/1-800-688-2534).

주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다. 612-676-6500/1-866-457-7144 (TTY: 612-676-6810/1-800-688-2534) 번으로 전화해 주십시오.

PAUNAWA: Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nang walang bayad. Tumawag sa 612-676-6500/1-866-457-7144 (TTY: 612-676-6810/1-800-688-2534).